



Occlutech GmbH ■ Winzerlaer Straße 2 ■ 07745 Jena ■ Germany

FSN identifier: FSN-2026-001
FSCA identifier: FSCA-2026-001

Date: 2026-07-01

To: Distributors, Hospitals, Physicians

Field Safety Notice

Affected Product: Figulla Flex II ASD Occluder and its Procedure Pack
REF: 29ASD12, 29ASD15, 29ASD19

FSN Identifier : FSN 2026-001
Type of action: Notification of labelling discrepancy

Attention:

Occlutech is providing information on a discrepancy in labelling regarding compatible Occlutech Delivery Set III (ODS III) sizes for certain Figulla Flex II ASD and its Procedure Packs. This labelling discrepancy does not pose an inherent risk as the product is safe to use with corresponding information on the label.

Details on affected devices:

Product name: Figulla Flex II ASD Occluder and its Procedure Pack
Please refer to Attachment *FSN-2026-001_List of affected products* for further product details

Dear Customer,

This Field Safety Notice is to inform you that Occlutech has initiated a voluntary Field Safety Notice for the products listed on the Attachment *FSN-2026-001_List of affected products*. This Field Safety Notice is limited to the serial numbers listed in the attachment.

Description of the problem:

Labels for two different compatible Occlutech Delivery System (ODSIII) sizes are visible on the Tyvek pouch of the affected products (implants). The implant is compatible with both ODS III sizes, which was demonstrated in bench tests. Therefore, this labelling discrepancy does not pose an inherent risk as the implant is safe to use with either information on the label.

Actions to be taken by the distributors, physicians and/or hospitals:

1. Inform clinicians and users of the label discrepancy regarding compatible ODS III sizes.
2. A written confirmation of the receipt, the reading and understanding of this Field Safety Notice should be provided to order@occlutech.com, or to your local sales representative compiling the attached confirmation form. If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.



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Recommendation:

Either the distributor or hospital should attach a copy of this Field Safety Notice to the outer box of any affected products to serve as a reminder.

Transmission of this Field Safety Notice:

This notice needs to be shared with users (physicians and/or hospitals) of the affected devices. Please assure and maintain awareness of this FSN among users of the affected Figulla Flex II ASD Occluder and its Procedure Pack products to ensure proper use of products.

Action to be taken by Occlutech:

Occlutech has taken all necessary steps to notify relevant authorities and has implement corrective and preventive actions.

Contact reference:

Customer Service

Occlutech International AB
Landskronavägen 2
SE-252 32 Helsingborg
Sweden
Tel: +46 766 36 72 00
E- mail: order@occlutech.com

Please do not hesitate to contact Occlutech with questions concerning this FSN.
We apologize for these inconveniences and are working to resolve the issue as soon as possible.
We trust that this document clarifies all concerns.

Nils Kästner
Vice President Regulatory Affairs and Quality
Occlutech GmbH



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Attachment *FSN-2026-001_List of affected products*

Serial Number	REF	Product name / description	Manufacturing date	Expiry date
2548291526_02	29ASD15	Figulla Flex II ASD, size 15	2022-06-23	2027-05-25
2547291248_01	29ASD12	Figulla Flex II ASD, size 12	2022-03-31	2027-03-02
2548291526_01	29ASD15	Figulla Flex II ASD, size 15	2022-06-23	2027-05-25
2548291526_04	29ASD15	Figulla Flex II ASD, size 15	2022-06-23	2027-05-25
2548291535_02	29ASD15	Figulla Flex II ASD, size 15	2022-07-07	2027-06-08
2548291535_03	29ASD15	Figulla Flex II ASD, size 15	2022-07-07	2027-06-08
2547291969_01	29ASD19	Figulla Flex II ASD, size 19,5	2022-04-13	2027-03-15
2547291247_01	29ASD12	Figulla Flex II ASD, size 12	2022-04-05	2027-03-07
2548291535_01	29ASD15	Figulla Flex II ASD, size 15	2022-07-07	2027-06-08



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FSN Confirmation form

1. Field Safety Notice (FSN) information	
FSN Reference number	FSN-2026-001
FSN Date	2026-06-25
Product/ Device name	Figulla Flex II ASD
Affected articles / REF	29ASD12, 29ASD15, 29ASD19
Affected LOT / SN Number	See <i>FSN-2026-001_List of affected products</i>

2. Customer (Distributor / Hospital / Physician) identification*	
Customer / Organisation Name	
Customer / Organisation Address	
Department/Unit (if applicable)	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Confirmation*	
With my signature below I confirm receipt, the reading and understanding of the Field Safety Notice. I confirm that I followed the recommendation to attach a copy of the Field Safety Notice to the outer product box.	
Print Name	
Signature	
Date	



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4. Return acknowledgement to sender	
Email	info.mdso@occlutech.com
Postal Address	Occlutech GmbH Winzerlaer Straße 2 07745 Jena GERMANY
Fax	+49 (3641) 508 358
Deadline for returning the completed form*	10 days after receipt the Field Safety Notice

*Mandatory fields are marked with **

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the actions.